



## DEVICE DETAILS

<b>NAME OF DEVICE</b>	ACT-8000 MEDACCU INFRARED EAR THERMOMETER
<b>ESTABLISHMENT NAME</b>	REVO HEALTHCARE SDN BHD
<b>ROLE OF ESTABLISHMENT</b>	AUTHORIZED REPRESENTATIVE
<b>REGISTRATION NO</b>	GB33173159217
<b>BRAND NAME</b>	MEDACCU
<b>MEDICAL DEVICE CATEGORY</b>	MD 0104 - Non-active medical devices with measuring function
<b>DEVICE GROUPING TYPE</b>	SYSTEM
<b>DEVICE DESCRIPTION</b>	<p>THE INFRARED EAR THERMOMETER ACT8000 IS A HAND-HELD DEVICE POWERED BY BATTERIES AND DESIGNED TO MEASURE HUMAN BODY TEMPERATURE THROUGH THE USER'S EAR CANAL. THE THERMOMETER CALCULATES THE TEMPERATURE OF THE USER BY CONVERTING INFRARED ENERGY EMITTED FROM THE USER'S TYMPANIC MEMBRANE (EARDRUM) TO A TEMPERATURE MEASUREMENT. THE TEMPERATURE MEASURED FROM THE EARDRUM HAS FOUND TO BE A CLINICALLY RELIABLE INDICATOR OF BODY'S CORE TEMPERATURE. A THERMISTOR IS USED TO DETECT THE AMBIENT TEMPERATURE WHILE A THERMOPILE IS USED TO DETECT THE INFRARED ENERGY EMITTED FROM THE PATIENT'S EARDRUM. THE DIFFERENCE BETWEEN THE AMBIENT AND EARDRUM TEMPERATURE CREATES A VOLTAGE DIFFERENCE THAT IS PROGRAMMED TO CONVERT INTO THE PATIENT OR USER'S TEMPERATURE READING.</p>
<b>DEVICE INTENDED PURPOSE</b>	<p>INFRARED EAR THERMOMETER ACT8000 IS A MEDICAL INSTRUMENT INTENDED FOR COMMON USERS AND DOCTORS TO MEASURE THE TEMPERATURE OF A PATIENT IN ORDER TO MONITOR AND/OR PREVENT ANY HEALTH CONDITION CAUSED BY OR RESULTING IN ABNORMAL BODY TEMPERATURE. IT IS DESIGNED TO GIVE A FAST AND PRECISE RESULT OF HUMAN'S BODY TEMPERATURE. IT IS USED ALONG WITH A ONE-TIME, SINGLE USE PROBE COVER, MEDACCU PROBE COVER FOR INFRARED EAR THERMOMETER THAT CONTACTS THE PATIENT'S EAR CANAL FOR HYGIENIC PURPOSES.</p>
<b>VALIDITY DATE OF REGISTRATION</b>	27/02/2017 - 26/02/2022

## LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Infrared Ear Thermometer	ACT8000
2	Digital Thermometer Probe Cover	IR20



# MEDICAL DEVICE AUTHORITY